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POB 1252

Avon Park F'L 33826

November 18, 1999

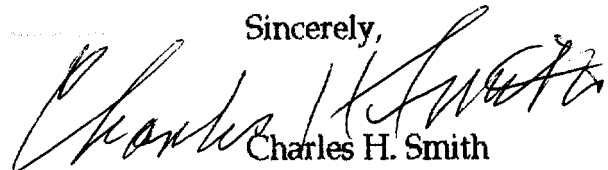
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dockets Manager:

Enclosed find letter addressed to Senators: Connie **Mack**, Bob Graham; Congressman Charles Canady and other significant Senatorial and House committee members. My letter is self-explanatory.

My plea to you is to extend to them the courtesy of a response to the concerns expressed in my letter. We have worked too long and too hard for closure of our eye bank programs to occur, especially if it does so without clear and undisputed cause.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles H. Smith".

Charles H. Smith

97 N - 4849

C/10

Copy to FDA

United States Senate
Washington+ D.C.

POB 1252
Avon Park FL 3382
November 18, 1999

Dear **Senator Mack**:

Information has come to me that the FDA has proposed a **new** Rule: "Suitability Determination For Donors of Human Cellular and Tissue Based Products" per 21 CFR Parts **210, 216, 820** and 1271. (Docket No.97N-4845).

The proposal would require a medical history review for evidence of Creutzfeldt Jacob Disease (**CJD**).

I ask you **to** have the FDA disclose **who**, or **what** premise or interest prompted this **proposal**. This proposal has the potential of practically shutting down the services of eye banks nationwide. Thousands of individuals would be **denied** restoration of sight through corneal transplants, or treatment of glaucoma through surgical use of **sclera** tissue. The risk factor must be debatable at the least or more specifically questionable when placed against the historical data of successful corneal transplants.

An example of success: Florida Lions Eye Bank, in association with Bascom-Palmer Eye Institute, (a Department of the School of Medicine, University of Miami), has provided corneal tissue over thirty (**30**) years to more than 30,000 transplant recipients. Current protocol requires preuse medical testing of body fluids for HIV and Hepatitis B and detailed examination of tissue condition by Institute doctors. I am not aware of any incident involving (**CJD**) being passed on to transplant recipients.

Our organization represents thirty years of volunteer efforts by **hundreds** of Lions engaged in supporting the Institute's operation. We not only seek donors and dollars, we organize sessions for training funeral directors in eye **enucleation** and inform the public of importance of eye donors. We are proud to **have** continued, for thirty years, **all** services with **no fees** whatsoever!!

My concern is directed to the extra time, effort, retraining and funds required to complete a possibly unnecessary medical history review of each donor. **TIME** is of the essence in maintaining viability of the tissue. An additional day or two to the **current** retrieval protocol could verifiably result in hundreds of individuals losing an opportunity for sight restoration.

I question 'Why now?' is it so essential to delve into family medical histories? Are we chasing a "ghost"? If so, who wins? I don't have to guess how many will lose, I know!

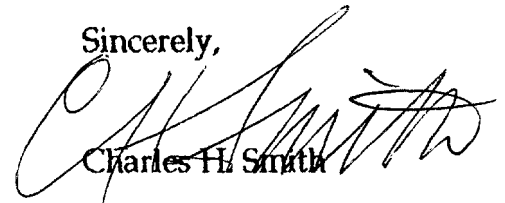
The undersigned is a Past President of the referenced Eye Bank and along with many other Lions, has given countless years, miles, and dollars in promotion and support of this sight-giving endeavor. He prays this history of service, sight and philanthropy is not in vain.

Your inquiries and assistance can be directed to the FDA, with arrival prior to December 15, 1999. Mailing address is:

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Your attention and a reply would be appreciated very much.

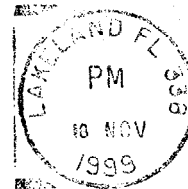
Sincerely,



Charles H. Smith

cc: FDA ~
Senatorial Committees
House Committees
Members of Congress, Florida delegation

CHARLES H. SMITH
P.O. BOX 1252
AVON PARK, FL 338264262



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